REMARKS

Applicant thanks the Office for the attention accorded the present Application in the June 4, 2008, Office Action. In that Action, Claim 2 was objected to for informalities, Claims 1 and 5 were rejected under 35 USC §103(a) as being unpatentable over Millenson (EP 0 717 283 A2) in view of Wright (US 2004/0002872), and Claims 2-3 were rejected under 35 USC §103(a) as being unpatentable over Millenson in view of Wright and further in view of Zwanziger et al. (WO 95/33996).

Applicant's Statement of Substance of Interview

Applicant thanks the Office for the courtesy shown to the undersigned in the July 10, 2008, telephonic interview relating to the rejection of the claims mailed on June 4, 2008. The interpretation of the prior art was discussed. Possible claim amendments were proposed to overcome the prior art and the proposed amendments appeared to overcome the prior art. Agreement was also reached with regard to independent Claim 1 being generic with regards to the election of species.

Claim Objection:

Applicant traverses the Office's objection to Claim 2 for informalities. Claim 2 uses a Markush group to limit the selection of the risk markers. The proper format of a Markush group includes the words "selected from the group consisting of." (emphasis added). See MPEP §803.02, first sentence. The Office suggests changing the terms "the group" to "a group," which is contrary to the prescribed wording for a proper

Markush group. In light of the preceding argument, Applicant respectfully requests that the objection as to Claim 2 be withdrawn.

35 USC §103(a) rejections:

The Office rejected Claims 1 and 5 under 35 USC §103(a) as being unpatentable over Millenson in view of Wright. The Office states that Millenson discloses a diagnostic and directed medication system except for expressly disclosing the drug metabolism test component and written prescription instruction are configured to predict adverse drug reactions to a prescribed medical therapy. The Office also states that Wright teaches a directed medication system including a drug metabolism test component (402C) and a written prescription instruction (402B) configured to predict adverse drug reactions to a prescribed medical therapy. The Office further states that all the claimed elements are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Applicant respectfully traverses.

Applicant has amended Claims 1 and 5 to include the limitations that the directed medication system is based upon the identification of predefined drug metabolism risk markers and that the second instruction directs the user to obtain a prescribed medical therapy containing a prescription for a medication based on the test result of the drug metabolism test component. Specifically, the medication is selected based on the test

result to minimize the probability of causing an adverse drug reaction when the medication is taken by the user.

The written prescription instruction component of the directed medication system includes the limitation that the prescription instruction component has a first instruction to obtain the drug metabolism test component and follow the test component instructions for submitting a sample for testing and a second instruction that directs the user to obtain a prescribed medical therapy that contains a prescription for a medication based on the result of the test where the medication is selected to minimize the probability of an adverse drug reaction being caused by the user taking the prescribed medication.

It should be noted that most medical test kits on the market today are used for determining events that have already occurred. (See Applicant's disclosure, paragraph [0006]). Applicant's directed medication system, however, is a system based on the identification of predefined drug metabolism risk markers to predict the potential for an adverse medical event before a medical event occurs (i.e., an adverse drug reaction). Specifically, Applicant's directed medication system determines those medications that could cause a bad reaction in a user to a medication taken by the user thereby enabling one to avoid or minimize such a reaction caused by the medication. Applicant's directed medication system is a proactive testing system, not a reactive testing system. Applicant's amended claims now makes clear that the directed medication system is based on the identification of predefined drug metabolism risk markers.

The Millenson device is a diagnostic instrument for use in detecting a foreign

element in a blood sample. Specifically, it is a test kit to test for the presence of the HIV virus. This test, like most medical test kits on the market, is used to determine an event that has already occurred. The event that has already occurred is the contraction of the HIV virus, which is known to cause AIDS. There is no known cure for the disease.

Additionally, Millenson fails to teach the second instruction of Applicant's system. Millenson only teaches submitting a blood sample to determine whether the user has the HIV virus that causes AIDS and then calling the test center to obtain the results of the test.

In contrast, Applicant's test kit/system is not used to determine a foreign element in a user's biological sample. It is also not used to determine an event that has already occurred. Applicant's test kit/system is used to determine the presence of the risk markers in a user's biological sample, which are not foreign elements but are naturally occurring in the user's biological makeup, that foretell the likelihood of an event occurring in the future if certain medications are prescribed to and taken by the user. In other words, Applicant's test kit/system will determine those medications that, if taken by the user, would likely produce an adverse drug reaction in the user. Consequently, a safer drug can be prescribed for a particular condition while minimizing the probability that the drug/medication itself would cause an adverse medical event.

Applicant's claimed invention includes a test component for receiving the user's biological sample and a written prescription instruction component that contains a first instruction and a second instruction. The first instruction directs the user to obtain the test component and follow the instructions provided with the test component for

submitting the user's biological sample. The second instruction directs the user to obtain a prescribed medical therapy that includes a prescription for a medication based on the test result of the test component where the medication selected is chosen to minimize the probability of an adverse drug reaction being if the particular medication is taken by the user.

Millenson discloses a test component specific for determining the presence of the HIV virus but not a written prescription instruction component that instructs the user to obtain a prescribed medical therapy that includes a prescription for a medication based on the test result.

Wright discloses a PDA-based (i.e., handheld) prescription messaging system to provide a physician with a sponsor to finance the physician's use of the handheld device to electronically prescribe medications and facilitate electronic messaging between the physician and the sponsor. The prescription messaging system includes a host computer database that stores patient data, prescription data, drug data, and message data. Prescription data includes a patient's active prescriptions and the patient's most recent prescriptions. The drug data includes a FDA approved drug file, patient active drug data, patient allergy data, and harmful drug interaction data. (See paragraph 46). Basically, the Wright system is an electronic database and collecting system to receive a physician's prescription data and other patient data.

In Wright, no testing is done on a user to identify predefined drug metabolism risk markers to determine the potential of an adverse drug reaction to a particular

prescription medication based on the presence or absence of the predefined risk markers. Also, Wright fails to disclose a second instruction provided to the patient that directs the patient to obtain a prescribed medical therapy containing a prescription for medication based on test results from a test on the patient's biological fluid to identify predefined drug metabolism risk markers.

The method used and described in Wright relating to adverse drug events (ADEs) consists of ADEs based on known drug interactions or known patient allergies to drugs and which data is stored in a database for comparing to new prescriptions entered into the system by the physician for the patient. For an example showing how the Wright device can avoid an ADE based on drug interactions, see paragraph 65 where there is described the use of the Wright device by the physician. When the physician enters the prescription data for a newly prescribed drug A for a patient into the Wright device, the Wright device checks the drug interaction data and the patient active drug data in the database to inform the physician of the consequences of prescribing drug A to the patient who is already taking a drug B. For an example showing how the Wright device can avoid an ADE based on patient allergies to drugs, see paragraph 75 where there is described the use of the Wright device by the physician. When the physician enters the prescription data for a newly prescribed drug A for a patient into the Wright device, the Wright device checks the patient allergy data in the database to inform the physician of a possible ADE when the physician prescribes drug A to the patient who is allergic to drug A.

Neither Millenson nor Wright teach a system to minimize adverse drug events

based on the identification of predefined drug metabolism risk markers in a user's biological fluid. Millenson's test result (i.e., that the user has the HIV virus) is nothing more than patient data that could be stored in the Wright device.

Where Millenson and Wright fail to teach a second instruction to direct a user to obtain a prescribed medical therapy containing a prescription for a medication based on a test result to identify predefined drug metabolism risk markers in a user's biological sample, the Office has failed to establish a prima facie case of obviousness by failing to provide the missing, second instruction element as claimed by Applicant.

In light of the above amendments and arguments, Applicant respectfully submits that the 35 USC §103(a) rejection of Claims 1 and 5 have been successfully traversed. Allowance of these claims is therefore requested.

The Office has rejected Claims 2 and 3 under 35 USC §103(a) as being unpatentable over Millenson in view of Wright and further in view of Zwanziger et al. (WO 95/33996). The Office states that Millenson in view of Wright discloses the claimed diagnostic and directed medication system as set forth above but fails to expressly teach the one or more predefined drug metabolism markers being DNA or enzymes or the test component being a genomics-based test. The Office further states that Zwanziger teaches the drug metabolism markers being DNA or enzymes and the test component being a genomics-based test. The Office concludes that all of the component parts are known in Millenson in view of Wright and Zwanziger and that it would have been obvious to one having ordinary skill in the art at the time the invention

was made to combine the components as taught by Millenson with the components taught by Zwanziger to achieve the predictable results providing alternate diagnostic testing means in a diagnostic and directed medication system.

Applicant respectfully traverses.

Applicant reincorporates Applicant's arguments as they pertain to Millenson in view of Wright where both Millenson and Wright fail to disclose a written prescription instruction component having a second instruction that directs the user to obtain a prescribed medical therapy containing a prescription for a medication based on a test result that identifies predefined drug metabolism risk markers in a user's biological sample and, further, where the test component described in Millenson is a test (1) to determine the presence of a foreign element in the blood and (2) to determine an event that has already occurred (i.e., contraction of the HIV virus).

The Zwanziger home test kit is a chromatographic test kit that provides an indication of the presence or absence of a particular disease or physiological condition. The home test kit is an assay system that receives a sample from the user. The assay system produces a coded pattern indicative of the presence of or a different coded pattern indicative of the absence of a disease or physiological condition. Again, like Millenson, the Zwanziger device is a test (1) to determine the presence of a foreign element in the blood (HIV virus) or a naturally occurring substance that is produced in response to a foreign element in the blood (antibodies to the HIV virus) and (2) to determine an event that has already occurred (i.e., contraction of the HIV virus or other listed viruses/infections). It is not a test based on the identification of predefined drug

metabolism risk markers, which are naturally occurring in the patient's biological fluid and are not produced in response to a foreign element in the blood.

The Zwanziger test kit instructions only provide the user with instructions on how to obtain a blood sample, place it on the sample area of the test kit, and to call the testing center after completion of the test with the test kit code and color coding to receive the results of the test. Upon completing the test, the user must then make a telephone call to an interpretation center, disclose the test pattern along with a test kit identifier assigned to the assay system, and receive an interpretation of the coded pattern from the interpretation center. The user, while on the telephone call, may also receive verbal counseling, which may be appropriate in view of the interpretation of the coded pattern. The optional verbal counseling is related to HIV infections. This is clearly stated in Zwanziger in the background of the invention where it states that the application relates in particular to a test kit for home use in circumstances such as the detection of HIV infections where counseling is considered necessary or desirable in the event of a positive result.

Zwanziger, like Millenson, fails to disclose a written prescription instruction component having a second instruction that directs the user to obtain a prescribed medical therapy containing a prescription for a medication based on a test result to identify predefined drug metabolism risk markers in a user's biological fluid as a part of the test kit.

On the other hand, Applicant's directed medication system is (1) **not** a test system to determine the presence of a foreign element in the user's biological sample

or a naturally occurring substance produced by the user's body in response to the presence of a foreign element in the user's blood, and (2) **not** a test system to determine an event that has already occurred (i.e., the presence of a particular disease or physiological condition such as antibodies produced in response to the presence of a virus).

Applicant's claimed directed medication system is to determine whether a user's natural, biological makeup is susceptible to dysfunction caused by particular medications. Applicant's claimed directed medication system is based on the identification of predefined drug metabolism risk markers in the user's biological fluid and is designed to determine whether the patient, who is prescribed a medication used to treat a particular disease or physiological condition that the patient already knows exists, is more prone to have an adverse drug reaction to the prescribed medication if taken by the patient. Depending on the test results, the healthcare provider for the user can modify or change the medical therapy to minimize the potential for an adverse drug reaction.

In addition, Millenson's, Wright's, Zwanziger's and Applicant's devices are quite different in the problems to be solved. One would use either the Millenson or the Zwanziger device to determine the presence of a foreign element in the blood (i.e. a particular disease) and the Wright device to record the data from the tests performed in Millenson and Zwanziger. One would not use Applicant's claimed invention to determine the presence or absence of a particular disease.

The Zwanziger disclosure fails to disclose not only a written prescription

instruction component but also a second instruction that directs the user to obtain a prescribed medical therapy containing a prescription for a medication that minimizes the probability of organ dysfunction that can lead to an adverse drug reaction.

In light of the above amendments and arguments, Applicant respectfully submits that the 35 USC §103(a) rejection of Claims 2 and 3 have been successfully traversed. Allowance of these claims is therefore requested.

Where Claim 1 is deemed to be generic, Applicant also respectfully requests the reinstatement of Claims 4 and 6-19 of the Group 1 invention and allowance of these claims.

Applicant believes that all of the examined claims should now be in condition for allowance as well as the withdrawn claims of the Group 1 invention. Early and favorable action is respectfully requested.

The Examiner is invited to telephone the undersigned, Applicant's attorney of record, to facilitate advancement of the present application.

Respectfully submitted,

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